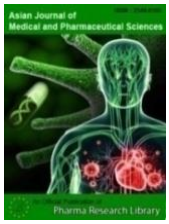

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A study on patient demographics and prescribing patterns of proton pump inhibitors in a tertiary Care hospital

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A B S T R A C T

Proton pump inhibitors represent a class of medications used to treat a wide variety of pathologies related to the stomach's acid production. This activity reviews the indications, action, contraindications for proton pump inhibitors as a valuable agent in managing acid-related disorders. The present study aimed to assess the appropriate use of Proton pump inhibitors in a tertiary care hospital. The prospective observational study was carried out for a period of 6 months. The study was conducted in a Gastroenterology department in a tertiary care hospital. In our study 25-35 years age patients were more 70 (58.33 %) as compared to other ages. In our study male patients were more 95 (79.16%) as compared to female patients were 25. PPI new users were more 68 (56.66%) as compared to PPI old users 52 (43.33%). The strong guidelines built on evidence-based indications and adequate daily doses would help the prescribers, in the hospital and in the community, to adequately prescribe and reduce misuse of PPIs. Integration of a prescription assistance programme in our computerized patient record system could help to identify the correct indication and the correct dose and limit the length of prescription (20.83 %).

Keywords: Proton pump inhibitors, stomach's acid production, evidence based indications, community, computerized patient record system.

A R T I C L E I N F O

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C o n t e n t s

1. Introduction

Proton pump inhibitors represent a class of medications used to treat a wide variety of pathologies related to the stomach's acid production. This activity reviews the indications, action, contraindications for proton pump inhibitors as a valuable agent in managing acid-related disorders. This activity will highlight the mechanism of action, adverse event profile, and other key factors (e.g., off-label uses, dosing, pharmacodynamics, pharmacokinetics, monitoring, relevant interactions) pertinent for members of the inter professional team in the treatment of acid-related disorders.

History

Evidence emerged by the end of the 1970s that the newly discovered proton pump (H+/K+ ATPase) in the secretory membrane of the parietal cell was the final step in acid secretion. Literature from anaesthetic screenings led attention to the potential antiviral compound pyridylthioacetamide which after further examination

pointed the focus on an anti-secretory compound with unknown mechanisms of action called timoprazole. Timoprazole is a pyridylmethylsulfinyl benzimidazole and appealed due to its simple chemical structure and its surprisingly high level of anti-secretory activity.

Optimization of substituted benzimidazoles and their antisecretory effects were studied on the newly discovered proton pump to obtain higher pKa values of the pyridine, thereby facilitating accumulation within the parietal cell and increasing the rate of acid-mediated conversion to the active mediate. As a result of such optimization the first proton pump inhibiting drug, omeprazole, was released on the market. Other PPIs like lansoprazole and pantoprazole would follow in its footsteps, claiming their share of a flourishing market, after their own course of development.

PPIs can be divided into two groups based on their basic structure. Although all members have a substituted pyridine part, one group has linked to various benzimidazoles, whereas the other has linked to a substituted imidazopyridine. All marketed PPIs (omeprazole, lansoprazole, pantoprazole) are in the benzimidazole group. Proton pump inhibitors are prodrugs and their actual inhibitory form is somewhat controversial. In acidic solution, the sulfenic acid is isolated before reaction with one or more cysteines accessible from the luminar surface of the enzyme, a tetracyclic sulfenamide. This is a planar molecule thus any enantiomer of a PPI loses stereospecifity upon activation.

Discovery

In the year 1975, timoprazole was found to inhibit acid secretion irrespective of stimulus, extracellular or intracellular. Studies on timoprazole revealed enlargement of the thyroid gland due to inhibition of iodine uptake as well as atrophy of the thymus gland. A literature search showed that some substituted mercapto-benzimidazoles had no effect on iodine uptake and introduction of such substituents into timoprazole resulted in an elimination of the toxic effects, without reducing the antisecretory effect. Addition of 5-methoxy-substitution to the benzimidazole moiety of omeprazole was also made and gave the compound much more stability at neutral pH. In 1980, an Investigational New Drug (IND) application was filed and omeprazole was taken into Phase III human trials in 1982. A new approach for the treatment of acid-related diseases was introduced, and omeprazole was quickly shown to be clinically superior to the histamine H2 receptor antagonists, and was launched in 1988 as Losec in Europe, and in 1990 as Prilosec in the United States. In 1996, Losec became the world's biggest ever selling pharmaceutical, and by 2004 over 800 million patients had been treated with the drug worldwide. During the 1980s, about 40 other companies entered the PPIs area, but few achieved market success: Takeda with lansoprazole, Byk Gulden (now Nycomed) with pantoprazole, and Eisai with rabeprazole, all of which were analogues of omeprazole10-18.

Indications

Proton-pump inhibitors (PPIs) represent a class of drugs most prominently known for their use in acid-related disorders. Omeprazole, a drug belonging to this class, is among the top 10 most prescribed drugs in the United States. PPIs are derivatives of the heterocyclic organic molecule benzimidazole. They are often the first-line agents amongst gastroenterologists for the following:

- Esophagitis
- Non-erosive reflux disease
- Peptic ulcer disease
- Prevention of nonsteroidal anti-inflammatory drug-induced ulcers
- Zollinger-Ellison Syndrome
- Part of the triple therapy regimen for Helicobacter pylori infections

The FDA has approved the following PPIs as of 2015:

- Omeprazole
- Esomeprazole
- Lansoprazole
- Dexlansoprazole
- Pantoprazole
- Rabeprazole

2. Methodology

The prospective observational study was carried out for a period of 6 months. The study was conducted in a Gastroenterology department in a tertiary care hospital. A written and informed consent was obtained from the recruited patients. A Total of 120 patients were enrolled in the study.

Study Design: It was Prospective observational study.

Study Period: The Present study was conducted for a period of six months.

Study site: The Present study was conducted in a Gastroenterology department of a tertiary care hospital.

Sample size: It was 120 Patients.

Inclusion criteria

- Patients with gastro intestinal abnormalities.
- Patients who are willing to give consent.

Exclusion criteria

- Patients below 18 years.
- Patients who were not willing to join in the study.
- Patients who are not diagnosed with gastro intestinal abnormalities.
- Special population including pregnant women and lactating women.
- Psychiatric abnormalities.

Institutional ethics committee (IEC) consideration:

The research protocol was submitted to ethical committee and ethical Committee was permitted to perform the research work in the Gastroenterology department.

Patient data collection and management:

The data collection form contains information regarding age, sex, BMI, diagnosis, past medical history, laboratory data, and diagnostic results. The information about risk factors, clinical laboratory reports, treatment, dose and frequency of administration and duration of therapy was collected from the patients treatment chart.

Statistical analysis:

The data was represented as percentages. The $P<0.05$ was considered to indicate a statistically significant difference.

3. Results and Discussion

Table 1: Age In our study 25-35 years age patients were 70 (58.33 %), 36-45 years age patients were 27 (22.5 %), 46-55 years age patients were 23 (19.16 %).

S.No	Age	Total N=120	Percentage (%)
1.	25-35	70	58.33
2.	36-45	27	22.5
3.	46-55	23	19.16
	Total	120	

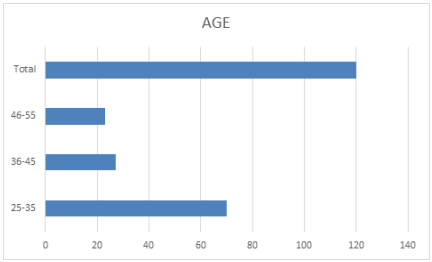

Figure 1: Age

Table 2: Gender: In our study male patients were 95 (79.16 %) and female patients were 25 (20.83 %).

S.No	Gender	Total N=120	Percentage (%)
1	Male	95	79.16
2	Female	25	20.83
	Total	**120**	

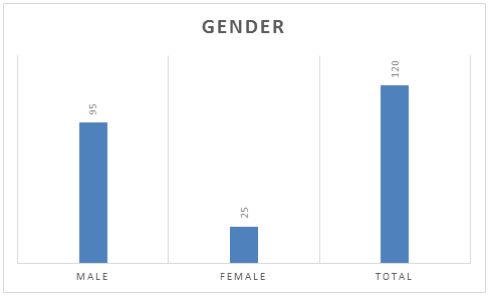

Figure 2: Gender

Table 3: Diet Vegetarian patients were 74 (61.66 %) and non-vegetarian patients were 46 (38.33 %).

S.No	Diet	Total N=120	Percentage (%)
1.	Vegetarian	74	61.66
2.	Non Vegetarian	46	38.33
	Total	**120**	

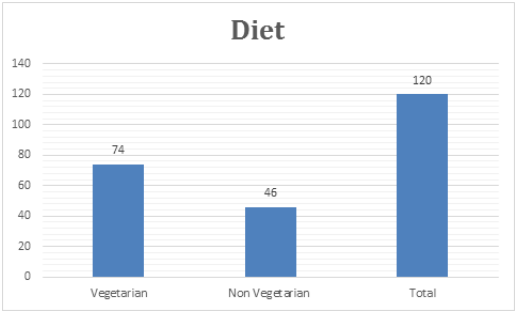

Figure 4: Diet

Table 4: Residential area In our study urban area patients were 72 (60 %) and rural area patients were 48 (40 %).

S.No	Residential area	Total N=120	Percentage (%)
1.	Urban	72	60
2.	Rural	48	40
	Total	**120**	

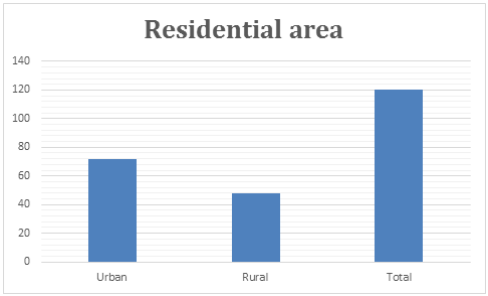

Figure 4: Residential area

Table 5: Social habits The smoking patients were 81 (67.5 %), and alcohol patients were 39 (32.5%).

S.No	Social habits	Total N=120	Percentage (%)
1.	Smoking	81	67.5
2.	Alcohol	39	32.5
	Total	**120**	

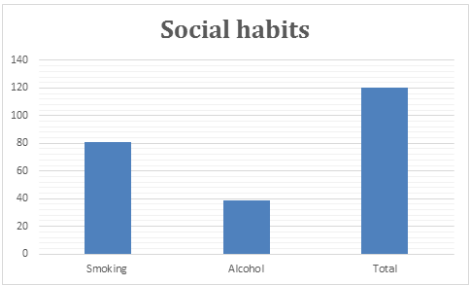

Figure 5: Social habits

Table 6: Marital status Marital status of study patients include single patients were 28 (23.33 %), and married patients were 58 (48.33 %) and widow patients were 34 (28.33 %).

S.No	Marital status	Total N=120	Percentage (%)
1.	Single	28	23.33
2.	Married	58	48.33
3.	Widow	34	28.33
	Total	**120**	

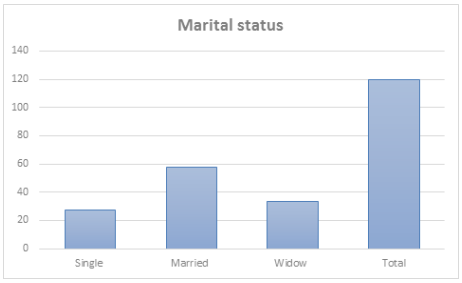

Figure 6: Marital status

Table 7: Number of drugs per prescription 1-2 Number of drugs per prescription was 22 (18.33%), 3-4 prescription drugs was 34 (28.33%), 5-6 prescription drugs was 18 (15 %) and 7-8 prescription drugs was 46 (38.33%).

S.No	Number of drugs	Total N=120	Percentage (%)
1.	1-2	22	18.33
2.	3-4	34	28.33
3.	5-6	18	15
4.	7-8	46	38.33
	Total	**120**	

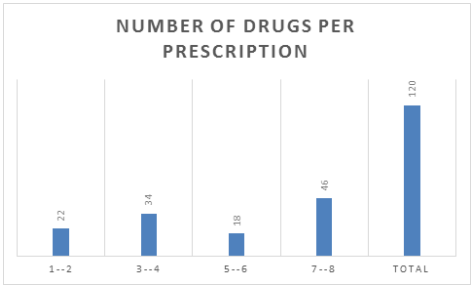

Figure 7: Prescription analysis of antimicrobial agents

Table 9: PPI Indication for Treatment PPI Indication for Treatment includes GERD diagnosis cases was 14 (11.66%), Upper GI diagnosis cases was 26 (21.66%), GIT Bleeding diagnosis cases was 38 (31.66 %), Peptic ulcer disease diagnosis cases was 23(19.16%),Gastritis diagnosis cases was 19 (15.83%).

S.No	Diagnosis cases	Total N=120	Percentage (%)
1.	GERD	14	11.66
2.	Upper GI	26	21.66
3.	GIT Bleeding	38	31.66
4.	Peptic ulcer disease	23	19.16
5.	Gastritis	19	15.83
	Total	**120**	

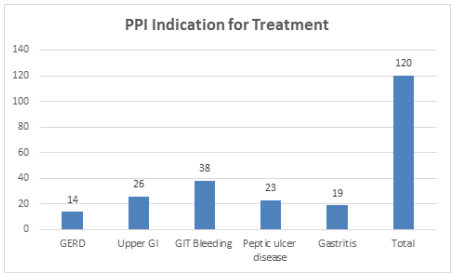

Figure 9: PPI Indication for Treatment

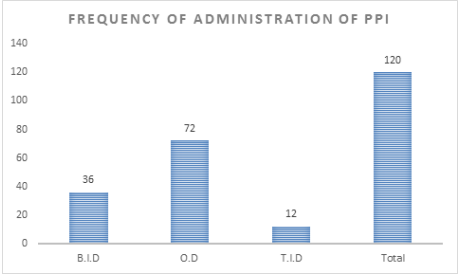

Figure 10: Frequency of administration of PPI

Table 10: Frequency of administration of PPI The Frequency of administration of PPI include BID patients were 36 (30%), OD patients were 72 (60 %), TID patients were 12 (10 %).

S.No	Frequency of administration of PPI	Total N=120	Percentage (%)
1	B.I.D	36	30
2	O.D	72	60
3	T.I.D	12	10
	Total	**120**	

Table 11: Duration of PPI use 1-3 days duration of PPI patients were 41 (34.16%), 4-7 days duration of PPI patients were 43 (35.83%), >7 days duration of PPI patients were 36 (30%).

S.No	Drugs	Total N=120	Percentage (%)
1.	1-3 days	41	34.16
2.	4-7 days	43	35.83
3.	>7 days	36	30
	Total	**120**	

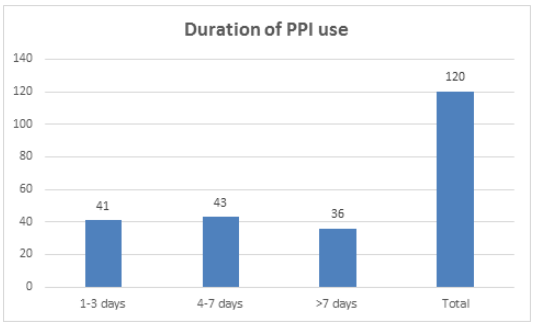

Figure 11: Duration of PPI use

Table 12: PPI USERS PPI old users were 52 (43.33 %) and PPI new users were 68 (56.66 %).

S.No	Prescribed Drugs	Total N=120	Percentage (%)
1.	Old users	52	43.33
2.	New users	68	56.66
	Total	**120**	

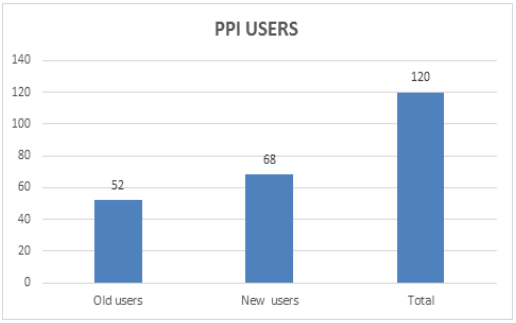

Figure 12: PPI USERS

Discussion

- In our study 25-35 years age patients were more 70 (58.33 %) as compared to other ages.
- In our study male patients were more 95 (79.16 %) as compared to female patients 25 (20.83 %).

- Vegetarian patients were more 74 (61.66 %) as compared to non-vegetarian patients 46 (38.33 %).
- In our study urban area patients were more 72 (60 %) as compared to rural area patients were 48 (40 %).
- The smoking patients were more 81 (67.5 %) as compared to alcohol patients 39 (32.5%).
- Married patients were more 58 (48.33 %) as compared to other marital categories[87-89].
- 7-8 prescription drugs was more 46 (38.33%) as compared to other drug prescprtions.
- The types of drug regimen include oral regimen was more 65 (54.16 %) as compared to Intravenous drug regimen 55 (45.83 %).
- GIT Bleeding diagnosis cases was more 38 (31.66 %) as compared to other diagnosis cases.
- The Frequency of administration of PPI include OD patients were more 72 (60 %) as compared to other drug frequency[90-96].
- 4-7 days duration of PPI patients were more 43 (35.83%) as compared to other duration of PPI.
- PPI new users **w**ere more 68 (56.66 %) as compared to PPI old users 52 (43.33 %).

4. Conclusion

The Careful monitoring of proton pump inhibitors needed to avoid serious drug interactions involving PPIs, and training programs should sensitize the clinicians on the evidence-based use of PPIs. The strong Guidelines built on evidence-based indications and adequate daily doses would help the prescribers, in the hospital and in the community, to adequately prescribe and reduce misuse of PPIs. Integration of a prescription assistance programme in our computerized patient record system could help to identify the correct indication and the correct dose and limit the length of prescription97-102. A thorough evaluation of proton pump inhibitors treatment according to their clinical utility and at discharge, reconsideration of the usefulness of the hospital treatment should also be considered. Finally, education and patient awareness could also significantly reduce the use of PPIs, especially in the long term is needed. The most frequent indication for PPI use was epigastric pain, while omeprazole was the highest utilized PPI. The significant factors associated with inappropriate PPI prescriptions were inpatients, epigastric pain, and IV PPI prescriptions. Thus, there is a need for the institution of a PPI-based stewardship program at the study hospital. Consequently, the clinical services of ward-based pharmacists are critical for its successful implementation.

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